



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0180]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0810. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for the Collection of Quantitative Data on Tobacco Products and
Communications

OMB Control Number 0910-0810--Extension

In order to conduct educational and public information programs relating to tobacco use as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA's Center for Tobacco Products will conduct research and use a variety of media to inform and educate the public, tobacco retailers, and health professionals about the health risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco.

To ensure that these educational and public information programs have the highest potential to be received, understood, and accepted by those for whom they are intended, the Center for Tobacco Products will conduct research and develop health messages relating to the control and prevention of disease. In conducting such research, FDA will use quantitative methods (i.e., surveys, experimental studies) for studies about tobacco products. These studies may be used to collect information related to foundational research informing message development or the formative pretesting of tobacco communication messages and other materials directed at consumers. This type of research involves: (1) assessing audience knowledge, attitudes, behaviors, and other characteristics for the purpose of determining the need for and developing health messages, communication strategies, and public information programs; (2) pretesting these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions; and (3) adding to the regulatory science knowledge base. Quantitative studies play an important role in exploring areas of research and gathering information because they can be used to summarize a population of interest on key variables or reveal systematic relationships between variables.

Foundational research to inform message development and the formative pretesting of messages are a staple of best practices in communications research. Obtaining voluntary

feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program. The purpose of obtaining information from formative pretesting is that it allows FDA to improve materials and strategies while revisions are still affordable and possible. Formative pretesting can also avoid potentially expensive and dangerous unintended outcomes caused by audiences interpreting messages in a way that was not intended by the drafters. By maximizing the effectiveness of messages and strategies for reaching targeted audiences, the frequency with which tobacco communication messages need to be modified should be greatly reduced.

The voluntary information collected will serve the primary purpose of providing FDA information about various measures of ad performance including message comprehension, perceived effectiveness, emotional responses and knowledge, attitudes, and behavior change to assess the ability of messages, advertisements, and materials to reach and successfully communicate with their intended audiences. Quantitative testing messages and other materials with a sample of the target audience will allow FDA to refine messages, advertisements, and materials directed at consumers while the materials are still in the developmental stage.

In addition, quantitative information is needed by FDA to track changes in response to policy and regulatory actions and to expand the tobacco regulatory science base by providing information on changing behaviors, knowledge, and attitudes about tobacco products, including postmarketing surveillance of tobacco products.

In the *Federal Register* of March 5, 2021 (86 FR 12952), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA related comment was received.

(Comment) The comment suggested specific types of messages that FDA should test and then implement in public health campaigns.

(Response) FDA appreciates the comment. The content and focus on studies submitted through this generic clearance will depend on Agency priorities and needs, which are not yet determined at this time.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Screeners	485,580	1	485,580	0.083 (5 minutes)	40,465
Self-Administered Surveys	133,728	1	133,728	0.33 (20 minutes)	44,576
Total					85,041

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Number of respondents to be included in each new survey will vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of activities that may be administered and estimated burden levels during the 3-year period. Time to read, review, or complete the activity is built into the “Average Burden per Response” figures. Our estimated burden for the information collection reflects an overall increase of 60,000 hours and a corresponding increase of 461,808 responses. We attribute the adjustment to an increase in the number of new quantitative studies that are anticipated underneath this information collection during the next 3 years (proposed extension).

Dated: September 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-20057 Filed: 9/16/2021 8:45 am; Publication Date: 9/17/2021]